



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,530	09/22/2003	Peter Fromherz	2923-566	5890

6449 7590 03/09/2006

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

MARTIN, PAUL C

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/666,530	Applicant(s) FROMHERZ ET AL.	
	Examiner Paul C. Martin	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-13 and 23 are pending in this application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 states a "medium which has a salt concentration of ≤ 100 mmol/L", however it is unclear whether this is *total* salt concentration or the concentration of any one of the component salts. The instant specification repeatedly refers to a "low sodium solution" (Pg. 2, Lines 7-10 and Pg 10, Lines 28-32). Claims 2-13 and 23 are indefinite as they are dependent on Claim 1.

Claim Rejections - 35 USC § 103

Applicant's arguments, see Pages 11-12, filed 02/07/06, with respect to the rejection(s) of claim(s) 1-13 under 35 USC §103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection of claims 1-13 and 23 is made in view of Fromherz *et al.* (WO/2001/07002) in view of Meme *et al.* (2001).

Fromherz *et al.* teaches a method for determining whether a substance is a modulator of a membrane-associated voltage-controlled, ligand controlled, or mechanically controlled ion-channel/receptor system. (Pg. 3, Lines 47-50, Pg. 2, Lines 9-12).

Fromherz *et al.* teaches that the ion channel is a potassium channel hSlo (Pg. 2, Lines 47-48), that the ion-channel receptor system contains NMDA receptor (Pg. 3, Lines 1-2), that stimulation of the target component can be carried out via electrical, optical, or chemical means (Pg. 3, Lines 4-11), as mentioned above an inherent characteristic of voltage is that it is in either AC or DC form.

Fromherz *et al.* teaches that the cell is in contact with an additional electrode, specifically a patch clamp (Pg. 5, Lines 20-22), that the potential sensitive electrode can be arranged on a chip, (Pg. 3, Line 16) and that a multiplicity of cells can be immobilized on a chip having a multiplicity of electrodes. (Pg. 5, Lines 18-19)

Fromherz does not teach the use of a medium, which has a salt concentration of ≤ 100 Mmol/L or the use of an array comprising a multiplicity of cells immobilized on different electrodes for the purpose of testing a multiplicity of substances.

Meme *et al.* teaches a method for determining whether a substance is a modulator of a target component in a cell, comprising the steps of:

Preparing a cell, containing a target component, wherein the cell is immobilized on a potential-sensitive electrode (Pg. 488, Column 1, Lines 31-41), bringing a substance to be tested in contact with the cell, in a medium which has a total salt concentration of ≤ 100 mmol/L (Pg. 488, Column 2, Lines 14-22 and Pg. 492, Fig. 4), measuring the signal at the electrode due to the target component, and determining the effect of the substance to be tested on the measurement signal (Pg. 492, Fig. 4).

It would have been obvious to combine the method Fromherz *et al.* for the determination of whether a substance is a modulator of a target component of a cell with the method as taught by Meme *et al.* for determining whether a substance is a modulator of a target component of a cell wherein the method utilizes a medium which has a salt concentration of ≤ 100 mmol/L because the method of Meme *et al.* showed a stronger and longer lasting response to a compound in the presence of a low salt solution. The ordinary artisan would have been motivated to apply the low salt solution of Meme *et al.* to the method of Fromherz *et al.* in order to test whether these effects would be found in alternate experimental situations. The ordinary artisan would have had a reasonable expectation of success based upon the demonstrated success of Meme *et al.* in using a low salt solution in a similar method as described by Fromherz *et al.*

It is noted *supra* that Fromherz *et al.* teach the method of cultivating a multiplicity of cells immobilized on multiple electrodes. It would have been obvious to the ordinary artisan at the time of the invention that if the technique were suitable for the testing of a single substance that it would take only a little further modification to practice the technique using multiple substances. The ordinary artisan would have been motivated to do so because a method of screening multiple substances would be more efficient and cost effective than simply screening one at a time, and the ordinary artisan would have had a reasonable expectation of success based on the previous success of the technique on testing a single substance.

Conclusion

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

Art Unit: 1655

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

03/03/06

PATRICIA LEITH
PRIMARY EXAMINER

